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(54) Abstract Title
Fixator for arteries

(57) A fixator for retaining a graft on an artery comprises an abutment portion for abutting the graft wall, and two elongate members extending therefrom, the elongate members being resiliently biased into a retaining configuration and moveable into an axial configuration to enable the fixator to be conveyed along an artery (Fig 2).

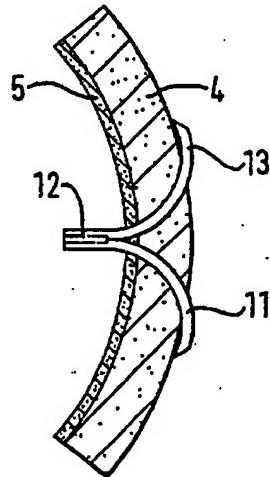


FIG. 4

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date but within the period prescribed by Rule 25(1) of the Patents Rules 1995.

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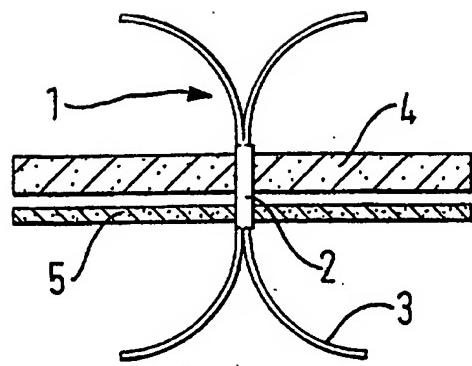


FIG. 1A

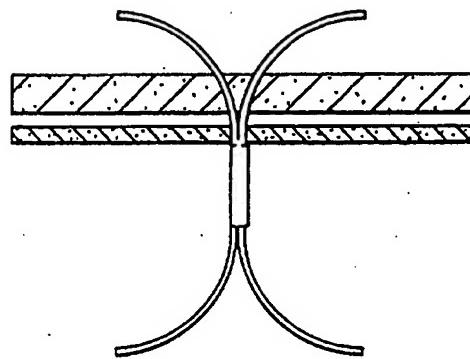


FIG. 1B

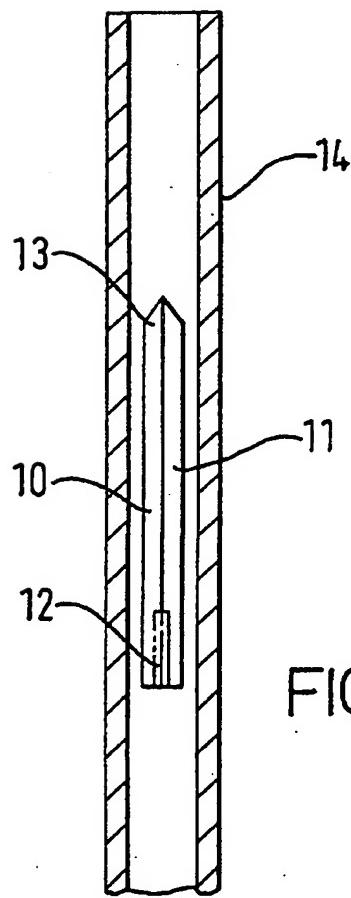


FIG. 2

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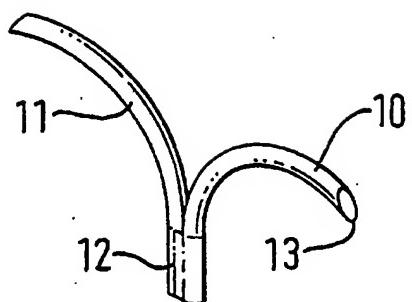


FIG. 3

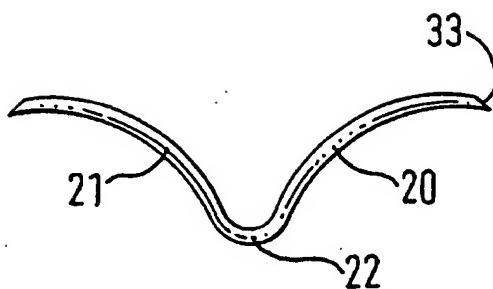


FIG. 5

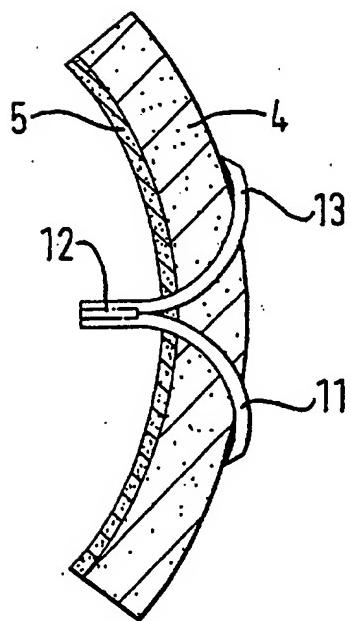


FIG. 4

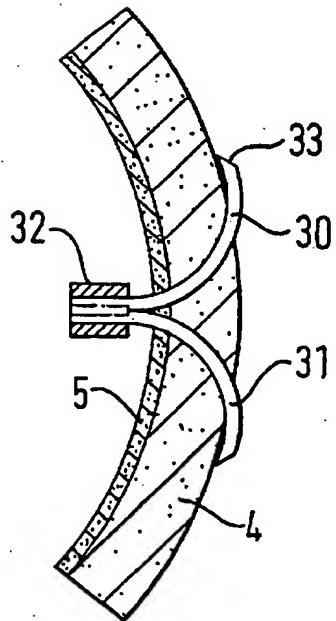


FIG. 6

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Fixator for the Repair of Articles

The present application relates to a fixator which can be used surgically to join living tissue or to attach graft material to living tissue. More specifically, it can be used to join 5 a vascular graft to an artery wall, preferably by minimally invasive or endolumenal means.

WO 92/05828 discloses a wire-form suture which comprises an open wire ring, the ends of which have been arranged to overlap. The wire-formed ring can be fully or partially 10 straightened, one end sharpened and the whole device driven through adjoining tissues. The wire has a spring or shape memory characteristic which causes it to re-form into a ring shape when in place thereby drawing together the tissues.

An improvement to this design is disclosed in PCT/GB99/02544 (in the name of the 15 present applicant), in which a pair of joined wires have a shape memory which causes them to form an 'H' shape upon deployment. This shape has the advantage of symmetry which ensures that the orientation of the fixator remains stable after implementation. It also has the advantage that the overall width of the fixator increases after implantation. This reduces the possibility of the fixator's pulling out from its implantation site. Both of 20 these advantages are particularly important in the critical application of intra-arterial implantation.

A requirement of the design disclosed in PCT/GB99/02544 is that the part of the fixator where the wires are attached to each other is intended to lie within the wall of the artery 25 and the graft with the divided parts of the fixator projecting beyond the artery walls and graft on both the luminal and the visceral sides. A consequence of this requirement is that the paired wires must remain in contact with each other along their lengths while they pass through the artery and graft. If they do not, then the fixator may not pass fully through the structures or the fixator may remove a core of material (due to its increased 30 width). This constrains the design of an appropriate delivery system and can increase the

risk of misplacement of the fixator. Such misplacement could have serious consequences for a patient.

- According to a first aspect of the present invention, there is provided a device for retaining a graft on an artery, comprising an abutment portion for abutting the graft wall, and two elongate members extending from the abutment portion, the ends of the elongate members distal from the abutment portion being adapted to pierce the graft and the artery wall, the elongate members being resiliently biased into a retaining configuration such that in use the graft is retained on the artery between the abutment portion and the distal ends of the elongate members, and the elongate members being moveable into an axial configuration in which said members are disposed substantially on an axis, to enable the device to be conveyed along an artery.

In a preferred embodiment there are only two elongate members extending from the abutment portion.

- According to a second aspect of the present invention, there is provided a method for retaining a graft on an artery, comprising providing a device as defined above, moving the elongate members into the axial configuration, conveying the device along the artery (preferably along a catheter) until it is inside the graft, driving the distal ends of the elongate members into the graft and then the artery such that the elongate members move away from the axial configuration and towards the retaining configuration as they pierce the graft and artery, and continuing to drive the device through the graft and artery until the abutment portion abuts the graft wall and the device is in the retaining configuration.
- The improved design disclosed here reverses the requirement of PCT/GB99/02544 so that the paired members of the fixator are separate as they pass through the walls of both the graft and the artery and they remain separate on the visceral side of the artery. A further improvement is that the part of the fixator where the paired members are connected lies within the lumen of the artery rather than in its wall. As a consequence there is no requirement of the delivery system to retain the paired members of the fixator in contact. Neither is there a requirement for a single, large hole to be made in the wall

of the artery in which the joined part of the paired members can lie. In these ways the improved design makes successful delivery more likely and reduces the risk of damage to the artery wall.

- 5 The fixator can be constructed from a number of materials including metals and plastics and it can be fabricated from separate components, cut from a single block of material, moulded, cast or otherwise constructed. An example of the device when constructed from wire is described below to illustrate the preferred features.

- 10 An improved fixator comprises at least two wires which can be constrained to be parallel, each wire having two ends, the wires being joined together at or near to one end by welding, braising or similar means. The second, free ends of the wires are sharpened with a bevel, trocar, diamond or similar point. The wires are fabricated from a material which has a spring or thermal shape memory such as nickel/titanium shape memory alloy
- 15 such that their unconstrained shape is a curved 'Y' or 'gull-wing' shape in which the base of the 'Y' is formed from the joined wires.

Typical dimensions of the device would be as follows:

DIMENSION	MAXIMUM	MINIMUM	PREFERRED
Wire Diameter	1.0mm	0.1mm	0.5mm
Weld Length	5mm	1mm	2mm
Wire Length	25mm	4mm	8mm

- 20
- In use, the fixator is pushed through a tube with its sharpened ends arranged to emerge first from the tube. The tube constrains the wires of the fixator to be almost parallel but ensures that the points of the wires are slightly separate before they penetrate the tissue. The fixator is ejected progressively from the tube and the sharpened tips of the fixator
 - 25 are driven by spring recoil or thermal shape recovery to become further and further apart as the fixator emerges from the tube. When used to attach a vascular graft to an artery wall after delivery from within the artery, the fixator is disposed so that the welded join

lies within the lumen of the artery and the sharpened tips of the fixator have penetrated both the fixator and the wall of the artery and have curved away from the midline of the fixator.

- 5 A number of variants of the fixator can be made. The fixator can be made from a single wire which has been more extensively formed (figure 4).

The connection between the wires can include a sleeve which supplies strength, radio-opacity and a mechanical stop to prevent the fixator from passing through the wall of the
10 artery.

Figure 1. Implant of PCT/GB99/0254, (A) correctly implanted and (B) incorrect placement resulting from paired members separating while passing through artery wall.

- 15 Figure 2. Improved fixator constrained within delivery tube.

Figure 3. Perspective view of improved fixator when deployed.

Figure 4. Sectional view of improved fixator implanted through a vascular graft and the
20 wall of an artery.

Figure 5. Alternative form of construction of improved fixator using a single formed wire..

- 25 Figure 6. Alternative form of improved fixator in which wires are connected with a sleeve made from a radio-opaque material.

CLAIMS

1. A device for retaining a graft on an artery, comprising an abutment portion for abutting the graft wall, and two elongate members extending from the abutment portion, 5 the ends of the elongate members distal from the abutment portion being adapted to pierce the graft and the artery wall, the elongate members being resiliently biased into a retaining configuration such that in use the graft is retained on the artery between the abutment portion and the distal ends of the elongate members, and the elongate members being moveable into an axial configuration in which said members are disposed 10 substantially on an axis, to enable the device to be conveyed along an artery.
2. A device as claimed in claim 1, wherein the abutment portion includes means for attaching a suture.
- 15 3. A device as claimed in claim 2, wherein said means is a loop formed in the abutment portion.
4. A device as claimed in any preceding claim, wherein there are only two elongate members extending from the abutment portion. 20
5. A method for retaining a graft on an artery, comprising providing a device as claimed in any preceding claim, moving the elongate members into the axial configuration, conveying the device along the artery until it is inside the graft, driving the distal ends of the elongate members into the graft and then the artery such that the 25 elongate members move away from the axial configuration and towards the retaining configuration as they pierce the graft and artery, and continuing to drive the device through the graft and artery until the abutment portion abuts the graft wall and the device is in the retaining configuration.



Application No: GB 0002970.2
Claims searched: 1-4

Examiner: Peter Trickey
Date of search: 8 January 2001

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): A5R (REL, RESC, RESX)

Int Cl (Ed.7): A61B 17/064; A61F 2/06

Other: Online: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
E, X	WO 00/07506 A2 (Anson) Figures 1-3, 5, and line 28 page 12 to line 5 page 13 and claims 1-12	1, 4

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|---|---|---|--|
| X | Document indicating lack of novelty or inventive step | A | Document indicating technological background and/or state of the art. |
| Y | Document indicating lack of inventive step if combined with one or more other documents of same category. | P | Document published on or after the declared priority date but before the filing date of this invention. |
| & | Member of the same patent family | B | Patent document published on or after, but with priority date earlier than, the filing date of this application. |